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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/828,923 | 04/21/2004 | Jose Castillo Deniega | IFLOW.063C3 | 5645 |

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| EXAMINER |
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MACNEILL, ELIZABETH

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| ART UNIT | PAPER NUMBER |
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3767

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| NOTIFICATION DATE | DELIVERY MODE |
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08/06/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

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|------------------------------|--|---------------------------------------|--|
| Office Action Summary | Application No. 10/828,923 | Applicant(s) DENIEGA ET AL. | |
| | Examiner ELIZABETH R. MACNEILL | Art Unit 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/18/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 June 2008 has been entered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1,2, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (US 5,425,723) in view of Tremulis (US 6,102,903).

Wang teaches an elongated non-porous tube having a uniform diameter with an infusion section (18) and connectable to a supply of liquid (via 30) outside of the patient and an inner member (38) with a plurality of exit holes for evenly distributing fluid before it exits the tube. Wang does not teach that the inner member is porous or becomes "saturated."

Tremulis teaches that it is known in the art that a tube with a plurality of small holes is an equivalent of a porous tube. " Usually, a plurality of infusion ports will be distributed

over the catheter body in a predesignated pattern, more usually the ports will be longitudinally and circumferentially spaced from each other about the catheter body. The number of ports and the spacing between adjacent ports will, of course, depend on a variety of factors, such as the function of the delivery catheter, the type and quantity of fluid being delivered, the size of the restriction or blockage, etc. For example, the catheter may have from 1 to 100 ports, usually from 3 to 30 ports, and the ports may be formed on only one side of the catheter body to specifically direct fluid towards one side of a fluid vessel. Alternatively, the catheter may have a multitude of tiny perforations (i.e., greater than 100) or the catheter may have a portion constructed of a porous material.” Bottom of Col 4 to top of Col 5.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a porous inner tube instead of an inner tube with a plurality of holes since it has been held that simple substitution of one equivalent for another is within the skill of an ordinary worker in the art.

2. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang/Tremulis in view of Burns (US 5,032,113).

Wang/Tremulis discloses the catheter as above, but do not disclose that the porous member is not concentric with the outer tube or a ring shaped bond at the middle portion of the infusion section. Burns discloses a catheter with inner (18) and outer (12) tubes wherein the outer tube and inner tube are not concentric (Fig 11 or Fig 13). Burns further discloses a middle bond (40, Fig 4B). It would have been obvious to one of

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ordinary skill in the art at the time the invention was made to make the tubes nonconcentric as a matter of obvious design choice.

3. Claims 4,6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang/Tremulis as applied to claim 1 above, and further in view of Abiuso (US 5,213,576).

Wang/Tremulis teaches the catheter as above but does not specify the pore size or ring shaped bonds at the proximal and distal ends of the infusion section.

Abiuso teaches an infusion catheter with porous insert (40) with pores of 15-30 microns and two ring shaped bonds (31 and 35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to select a pore size of 15-30 microns and bond the porous member to the tube in because it would be expected to evenly distribute medicament and prevent leakages from the ends of the infusion section.

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wang/Tremulis in view of Reynolds (US 5,370,610).

Wang/Tremulis discloses the invention as above but fail to teach an air filter in the flow path of the catheter. Reynolds discloses a catheter with an air filter in the flow path of a catheter (64). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include an air filter in order to prevent bacteria from entering the body.

Response to Arguments

Applicant's arguments with respect to claims 1-7, 9 and 10 have been considered but are not persuasive. Applicant has argued that proposed modification of Wang to include a porous tube (since porous tubes and micro machined holes are equivalents as taught by Tremulis) would change the mode of operation of Wang. Applicant is correct that Wang operates by adjusting the spacing between the inner and outer holes. See, for example, Wang at Col 2 line 29-37, "the ratio of the number of second ports to the number of first ports is higher in the distal portion than in the proximal portion of the catheter infusion section. In another narrower aspect, the first ports and second ports are positioned relative to one another so that the average fluid flow distance in the annular passageway between the second and first ports is smaller in the distal portion than in the proximal portion of the catheter infusion section." Applicant has argued that Wang requires a specific arrangement of inner holes but does not consider that the disclosure of Wang is broad enough to also teach that the outer holes are spaced farther apart in the proximal section and closer together in the distal section, thus changing the average fluid flow distance in the proximal versus distal sections. Therefore, the mode of operation of Wang is not changed by the modification of Tremulis. The rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767